Revoked by 85-3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

PR Notice 84-4

NOTICE TO REGISTRANTS OF PESTICIDES, APPLICANTS FOR PESTICIDE REGISTRATION, MANUFACTURERS AND FORMULATORS OF PESTICIDES

ATTENTION: Persons responsible for Federal Registration of Pesticides

Subject: Revised Procedures for Data Support Requirements under FIFRA

This notice announces revised procedures whereby applicants for pesticide registration, amended registration and reregistration may comply with the data support requirements of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq. (FIFRA). Recent court decisions enable the Agency to permit applicants once again to use citation of data with offer to pay as an acceptable means of complying with FIFRA sec. 3(c)(1)(D).

The revised procedures described in this notice may be used by applicants as of November 6, 1984. This notice supersedes PR Notice 83-4 and 83-4A, which are revoked effective November 6, 1984. These interim procedures will be in effect until final regulations published in the Federal Register of August 1, 1984 (49 FR 30884), become effective.

BACKGROUND

In order to obtain a pesticide registration (and, in some cases, an amendment to a registration, an applicant is required by FIFRA sec. 3(c)(1)(D) to submit or cite data which the Agency may consider in support of the application. FIFRA sec. 3(c)(1)(D) states that the application must contain "a full description of the tests made and the results thereof . . . or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator . . " Section 3(c)(1)(D) also imposes certain limitations on an applicant's right to cite, without permission, data which have been submitted by others.

Since the passage of the present FIFRA in 1978, EPA has implemented section 3(c)(1)(D) through procedures that reflect the various statutory requirements. But because the statutory provisions and EPA's implementation of them have been the subject of extensive litigation, the procedures have also reflected requirements imposed by judicial decisions. For a complete discussion of the history of EPA's implementation of FIFRA sec. 3(c)(1)(D), see the introduction to Pesticide Registration (PR) Notice 83-4 and the preamble to the Final Rule Establishing Application Procedures to Ensure Protection of Data Submitters' Rights, 49 FR 30884 (August 1, 1984).

Since June 30, 1983, registration applications have been submitted and evaluated under the procedures set forth in PR Notice 83-4 and 83-4A. Those procedures provided a means whereby applicants could fulfill the requirements of section 3(c)(1)(D) under the terms of federal district court injunctions which prohibited EPA from approving any applications which cited data in support of the application without the permission of the original data submitter. Those injunctions were imposed by district courts in Monsanto v. Acting Administrator, EPA, 564 F. Supp. 552 (E.D. Mo., 1983) and Union Carbide, et al. v. Ruckelshaus, 571 F. Supp. 117 (S.D.N.Y., 1983). EPA appealed both decisions to the United States Supreme Court, and the Supreme Court vacated both injunctions in mid-1984. In Monsanto, the Court issued an opinion upholding the constitutionality of section 3(c)(1)(D) and overturning the district court's holding that the provision worked a taking of property without just compensation. With respect to a separate holding that the mandatory binding arbitration provision of section 3(c)(1)(D) was unconstitutional for lack of sufficient provision for judicial review of arbitration decisions, the Supreme Court held that Monsanto's challenge was not ripe for litigation in the courts.

The Union Carbide injunction also was based on a holding that FIFRA provided insufficient judicial review of arbitration decisions. The Supreme Court vacated that injunction and remanded it to the district court for consideration in light of Monsanto. However, the district court reimposed its injunction in August 1984, and EPA again appealed to the Supreme Court, and asked the Court to stay the injunction pending completion of the appeal process. On October 9, 1984, the Supreme Court stayed the judgment of the district court. Consequently, the statutory provisions--which authorize registration applicants to cite previously submitted data without permission of the original data submitter--are no longer enjoined by any court.

PR Notice 83-4 stated clearly that the interim procedures it contained were adopted to respond to court rulings and were to remain in effect until final, effective rules are available to govern compliance with FIFRA sec. 3(c)(1)(D).

In its motion to the Supreme Court for a stay of the Union Carbide judgment, EPA stated:

EPA recently promulgated a final rule providing procedures for implementing the data licensing and data compensation provisions of Section 3(c)(1)(D). 49 Fed. Reg. 30884-30908 (August 1, 1984). That rule becomes effective upon completion of the 60-day statutory congressional review period. 7 U.S.C. 136w(a)(4). During the pendency of the Monsanto injunction, EPA implemented the data requirements aspects of registration through interim procedures under which applicants could establish that they had permission to cite any previously submitted data on which they rely. Pesticide Registration Notice 83-4 (and 83-4A). See 48 Fed. Reg. 32012 (July 13, 1983). If the injunction is stayed, EPA will immediately modify those interim procedures to permit applicants to establish either that they have permission to cite previously submitted data or that they have made a proper offer to pay for data compensation under Section 3(c)(1)(D). Accordingly, EPA will promptly implement the enjoined provision if the stay is granted.

This notice replaces PR Notice 83-4 and 83-4A and simply modifies the interim procedures in those notices to reflect the Supreme Court's actions vacating or staying the injunctions which had prevented implementation of the data-licensing provisions of section 3(c)(1)(D). These revised interim procedures, like PR 83-4, have been adopted to permit continued registration of pesticides pending the completion of rulemaking using the external review procedures required by FIFRA and the Administrative Procedure Act. That rulemaking process is now near completion, requiring only the completion of the statutory 60-day Congressional review period following promulgation. The rule, therefore, should be effective no later than March or April 1985.

Specifically, this notice repeats all of the elements of the interim procedures established in PR Notice 83-4 and 83-4A and supplements those elements with the procedures necessary to provide applicants with the means to cite previously submitted data without permission so long as they comply with the limitations and requirements of FIFRA sec. 3(c)(1)(D). (Some reorganization has been done for purposes of clarity.)

PROCEDURES

This portion of this Notice contains nine sections. Section I describes the applications to which the revised procedures apply. Section II describes the responsibilities of an applicant who relies on the Selective Method to satisfy the Agency's data requirements for registration. Section III describes the responsibilities of an applicant who relies on the Cite-All Method to satisfy data requirements. Section IV details the rights and obligations of data submitters under these procedures, and Section V explains how the Agency will review applications relying on these procedures. Section VI states how the Agency will handle challenges alleging non-compliance with these procedures. Section VII makes it clear that EPA's risk/benefit decisions are independent of data

support considerations. Section VIII explains how this notice affects pending applications. Section IX identifies persons to contact for further information.

In order to comply with the FIFRA sec. 3(c)(1)(D) requirements regarding data in support of applications for registration, an applicant may use the Selective Method or the Cite-All Method of data support, as described in these procedures.

An applicant who uses the Selective Method must submit a list of data requirements applicable to his product (see Section II.A. of this notice). He also must satisfy each data requirement (see Section II.B. of this notice) by (1) submitting (or citing) his own valid data, (2) citing valid data previously submitted to EPA by another, with the original submitter's permission or with a certification that a proper offer to pay compensation has been tendered to the original submitter, or (3) documenting that no data have previously been submitted which would meet the specific data requirement (Option 3 is not available in certain cases; see Section III.B.3. of this notice). An applicant may select a combination of these methods to fulfill the range of data requirements applicable to his product. Section II.C. of this notice describes an additional procedure by which an applicant may learn whether submitters of exclusive use data have provided data relevant to the applicant's product.

An applicant who uses the Cite-All Method may submit information showing that he has the written permission to rely on the data of all previous submitters of data concerning the product or its active ingredients or that he has tendered proper offers to pay compensation to all previous submitters of such relevant data who have not provided such permission. The procedures for the Cite-All Method are described in Section III of this notice.

I. Applications to Which these Procedures Apply

These procedures apply to all applications for registration, reregistration, or amended registration which are subject to the section 3(c)(1)(D) requirement to submit or cite data in support of such applications. EPA has previously described, in 40 CFR 162.9-1 (1983 edition), those types of applications which do not require compliance with the data support requirements. Although contained in regulations which are no longer in effect, that listing properly identifies the types of applications to which these interim procedures do not apply, and are repeated below. (See also 49 FR 30891-92 and 30903-04 (Aug. 1, 1984).

Applications which seek only one or more of the following types of amendments to existing registrations are not covered by these procedures, unless the Administrator or his designee finds that Agency consideration of scientific data would be necessary in order to approve the amendment under FIFRA sec. 3(c)(5):

(1) An increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately-added inert ingredients;

(2) A revision of the identity or amount of impurities present in the product;

(3) The addition or deletion of one or more deliberately-added inert ingredients;

(4) The deletion of one or more active ingredients;

(5) A change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;

(6) Deletion of approved uses or claims;

(7) Redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;

(8) Change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the change;

(9) Clarification of directions for use;

(10) Correction of typographical errors;

(11) Changes in the registrant's name or address;

(12) Adding or deleting supplemental registrants;

(13) Changes in the package or container size;

(14) Changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;

(15) "Splitting" a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously-approved use instructions (and related label statements) appropriate to a particular geographic region;

(16) Any other type of amendment, if the Administrator or his designee determines, by written finding, that Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and

(17) Compliance with Agency regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be cancelled or suspended under FIFRA sec. 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA sec. 3(c)(2)(B) or because of failure to submit data.)

II. The Selective Method.

A. Applicant's List of Data Requirements.

Each applicant who uses the Selective Method must submit with his application a list of the data requirements which he believes are applicable to the product he seeks to register. Where a Registration Standard has been issued for an active ingredient contained in the product, the applicable requirements for that active ingredient are listed in the Standard. If no such Registration Standard has been issued, the list must be based on the Agency's regulations in 40 CFR Part 158, "Data Requirements for Registration," promulgated on July 23, 1984. These regulations were published in the Federal Register on October 24, 1984 (49 FR 42856), and were submitted to Congress for the statutory 60-day review period. The method for determining the data requirements for registration is described in §§ 158.50 and 158.100(b). (Applicants seeking to register end use products should note that the "formulator's exemption" in FIFRA sec. 3(c)(2)(D) may eliminate many data requirements that would otherwise apply. See paragraph II.A.2.)

1. Data requirements for registration. When referring to the data requirements imposed pursuant to a Registration Standard, the applicant should list the requirements as they are set forth in the Standard. Information about any changes in those requirements which may have followed issuance of the Standard may be obtained from the Product Manager in the Registration Division.

When referring to 40 CFR Part 158, the applicant should select the general use pattern(s) (e.g. indoor use, terrestrial non-crop use, aquatic crop use) which best covers the use patterns specified in the proposed labeling of the pesticide product. The nine general use patterns on which most data requirements are based appear as the headings in the tables of data requirements contained in §§ 158.120 through 158.165. While it will usually be easy to determine which general use pattern(s) would be most appropriate, an applicant may refer to Appendix A of Part 158 for further guidance. Appendix A contains a list of several hundred specific use patterns and the corresponding general use pattern for each.

The applicant should next determine which specific types of studies are required for each of the general use patterns of his product, by referring to each of the tables of data requirements (e.g., § 158.120, which contains product chemistry data requirements, and § 158.155, which contains nontarget insect data requirements). The tables indicate for

each type of study and general use pattern whether data are usually required, indicated by [R] or R; conditionally required, indicated by [CR] or CR; or not usually required, indicated by a dash (--). The footnotes accompanying each table identify the specific circumstances under which each type of study is required. It is important to read the footnotes for each table.

Because of the "tiered" testing requirements of Part 158, an applicant may be unable to determine the applicability of some data requirements because imposition of the requirement depends on the results of other studies which are not known to him. In this case, the applicant may either assume that the data requirement applies to his product, or he may determine whether the requirement has been imposed on another registrant and therefore would be imposed on his product. To do the latter, the applicant would use the procedure for determining whether a data gap exists (see section II.B.3.). If the data have been submitted previously by any registrant, the Agency will presume that the data requirement applies to the applicant's product. If such data have not been submitted previously, an applicant for conditional registration will be required to submit the data if EPA determines that the data are needed to make an incremental risk finding under FIFRA sec. 3(c)(7)(B) or a no unreasonable adverse effects finding under FIFRA sec. 3(c)(5).

2. The "formulator's exemption". The applicant should determine whether he is eligible for the "formulator's exemption" in sec. 3(c)(2)(D) of FIFRA. Under this section, an applicant for registration of an end use product is excused from the normal section 3(c)(1)(D) requirement of submitting or citing data on the safety of any ingredient in the applicant's product which is present solely as a result of incorporation into his product (during formulation or packaging) of another product containing that ingredient which is registered under FIFRA and purchased from another producer.

An applicant who wishes to rely on the formulator's exemption must submit with his list of data requirements a fully completed "Formulator's Exemption Statement" (Attachment A). In addition, the applicant must submit or have on file with the Agency a current, complete, and accurate Confidential Statement of Formula (EPA Form 8570-4). Under FIFRA sec. 12(a)(1)(C), a change in the source of the purchased active ingredient is unlawful unless the registrant first obtains an amendment to his registration to identify the new source.

3. Waivers. Data required under Part 158 may be waived by EPA under some circumstances. The Agency normally will not require an applicant to satisfy a data requirement that has previously been waived for a pesticide similar to the applicant's product. To facilitate requests for such waivers, EPA will make available, upon request, all lists of data waivers it has prepared for active ingredients. (Lists generally will be available for chemicals for which EPA has established Registration Standards — 90 such standards have been developed to date — and for many new active ingredients registered since 1978. The Agency notes, however, that it will not develop such lists solely for purpose of these procedures, and that for most ingredients there are no such lists.) An

applicant seeking a waiver should indicate on the list of data requirements for his product that a requirement has previously been waived for a similar product, document the existence of the previous waiver, and briefly explain why that waiver should be extended to his product.

While these interim procedures are in effect, and until final regulations are effective, the Agency will consider requests for new waivers only when the applicant would actually be required to generate data in order to obtain registration. Thus, for example, an applicant for registration of a new use of a currently registered product may request that EPA waive some or all of the data pertaining to the new use. EPA does not expect to issue many waivers of this kind.

4. Form of the list. Each type of data requirement on the applicant's list shall be identified by the description contained in the Registration Standard or in the columns headed "Kind of data required" in Part 158. They should be listed in the same order as they appear in the applicable Registration Standard or in Part 158. Each list of data requirements shall include a subheading for each group of studies listed in a separate table of data requirements (e.g., toxicity studies, environmental fate studies). Finally, the list shall indicate how the applicant is satisfying each data requirement.

B. Satisfying the Data Requirements.

An applicant using the Selective Method may satisfy a data requirement by one or a combination of the following methods: (1) submitting valid "new" data; (2) citing valid data previously submitted by the applicant; (3) citing valid data previously submitted by another person, with the original data submitter's permission; (4) citing valid data not entitled to exclusive use[1/] which were previously submitted by another person, and submitting a certification that a proper offer to pay has been tendered to the original data submitter; or (5) in certain cases, showing that a "data gap" exists. These are further discussed below.

1. Submitting new data. New data must be submitted in the form of individual studies, each study addressing a single data requirement as listed in the Registration Standard or Part 158, and accompanied by the supplemental materials listed below.

a. A title page which includes the name of the study, identification of the test substance, the author(s), the date completed, the name and address of the laboratory (if any) that performed the study, and any laboratory codes or identifiers. Each submission of new data must also be identified as to the submitter of such data, the date of submission, and the registration number or file symbol (if known) of the EPA action for which submitted.

1/ FIFRA sec. 3(c)(1)(D)(i) specifies which data are entitled to "exclusive use" protection.

b. If any claims of confidentiality under FIFRA sec. 10(d)(1)(A), (B), and (C) are made, the passage(s) within the study for which the claim is made must be isolated from the study in a confidential attachment. The attachment must have a cover page that clearly indicates its confidential status under section 10(d). Further, the claimant must indicate the basis under FIFRA sec. 10(d)(1)(A), (B) or (C) for the claim of confidentiality. Information claimed confidential under FIFRA sec. 10(b) must be clearly identified within the main study but need not be isolated in a confidential attachment.

c. A certification with respect to Good Laboratory Practice standards, meeting the requirements of 40 CFR 160.12;

d. If the study is not in English, a complete and accurate translation of the study as well as the original language report.

2. Citing previously-submitted data. Applicants should not resubmit data previously submitted to the Agency. Rather, such data should be cited with the following information:

a. The identifying information required by paragraph II.B.1.a. above, to the extent it is known to the applicant.

b. When known, EPA's Master Record Identification (MRID) number; if the MRID number is not known, EPA's data catalogue accession nuumber.

c. The original submitter's identity;

d. The date on which the cited data were originally submitted to EPA or its predecessor agency;

e. The registration number, file symbol, experimental permit number, or petition number for which the data were originally submitted;

f. If the data being cited were originally submitted by a person other than the applicant, either: (1) evidence that all rights to the data have been permanently transferred to the applicant; or (2) a written statement signed by an authorized representative of the original data submitter giving the applicant permission to cite the data in support of the application or (3) a certification that a proper offer to pay compensation has been tendered to original data submitters who are not entitled to exclusive use protection (an acceptable statement for this purpose is provided as Attachment B to this Notice). A proper offer to pay compensation must offer to pay in accordance with FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D). Proper offers to pay must be tendered directly to the appropriate data submitters by certified mail and to EPA through the general offer to pay statement set forth in Attachment B to this notice.

3. Showing that a data gap exists. An applicant for conditional registration may wish to demonstrate that a data gap exists for a particular data requirement established in 40 CFR Part 158 — i.e., that no one has previously provided such data to the Agency — and that under the conditional registration provisions of FIFRA sec. 3(c)(7), registration would be proper notwithstanding the data gap. (If EPA needs the data to perform an incremental risk assessment, EPA will require submission of the data. See FIFRA sec. 3(c)(7)(B).) If an applicant wishes to claim that a data gap exists, he shall certify that he has no basis for believing that data meeting the data requirement have been submitted by any other person. He shall also certify that he has provided notice by certified mail, return receipt requested, to every person appearing on the List of Pesticide Data Submitters by Chemical (the "Data Submitters List") for each active ingredient in his product for which he claims a data gap exists[2/] and that he has waited at least sixty days following the provision of any such notice. An acceptable certification statement is included as Attachment C to this notice.

The notice to data submitters shall include:

a. A statement that the applicant intends to apply for registration or amended registration of a pesticide under FIFRA sec. 3(c)(7) using the Selective Method described in this notice, and that he intends to claim to be excused from the requirement of submitting certain data because of the existence of data gaps, as allowed by this Notice;

b. A list of the data requirements (by type of study and test substance) for which the applicant intends to claim that a data gap exists;

c. A request that, within 60 days of receipt, the data submitter identify, in the manner specified in this Notice, each valid study that the data submitter has previously submitted to EPA (or to its predecessors) and that would satisfy any of the requirements the applicant has listed.

If the Agency issues a registration on the assumption that a data gap exists for a particular data requirement, and if it is subsequently determined that valid data had been submitted concerning that requirement of which the applicant had been notified in a timely manner, the procedures specified in section VI. shall apply to such registration.

2/ In the event that the notice cannot be delivered to a data submitter, the applicant must describe the efforts which were made to provide notice.

C. Notice to Exclusive Use Data Submitters.

An applicant may send a certified letter, return receipt requested, to submitters of exclusive use data pertaining to an ingredient in the applicant's product notifying them that the applicant seeks to register a pesticide intended for specified uses and containing specific active ingredients on which the submitters have previously submitted data. A recipient of such a letter shall have 60 days in which to transmit to the applicant a list of the data which the data submitter believes are required for such a product. In addition, a data submitter may choose to send a copy of this list to EPA.

If a data submitter fails to make a timely response to the applicant, the data submitter will be presumed to have waived certain of his rights to challenge registration of the applicant's product. Specifically, where a list of data requirements is requested by the applicant, the data submitter may not challenge the applicant's failure to list a requirement that was not contained on the responsive list of data requirements prepared for the applicant's product by the data submitter until after the application has been approved. This section does not limit a data submitter's right to challenge a registration action after the Agency has issued the registration.

The presumption that the data submitter has waived his rights to challenge a registration prior to its issuance may be overcome by a showing that there was good cause for the data submitter's failure to respond in a timely manner and that the data submitter responded as promptly as possible under the circumstances.

III. The Cite-All Method.

As an alternative to the Selective Method in Section II, an applicant may satisfy the Agency's data requirements by providing information showing that he has chosen to rely on all data relevant to his product which have previously been submitted to EPA. Applicants using this method who are eligible for the formulator's exemption should first comply with the procedures described in II.A.2. above. In order to use the Cite-all Method of fulfilling the data requirements, the applicant must:

(A) Provide a letter, or other appropriate documentation, signed by an authorized representative of each prior data submitter giving the applicant the right to cite any relevant data that the data submitter has provided to EPA; or

(B) Provide a certification that he has made a proper offer to pay to all prior data submitters from whom he has not obtained and submitted proof of permission to cite any applicable previously submitted data. Where data are entitled to exclusive use protection, evidence of permission to cite the data is required.

An acceptable certification that offers to pay have been tendered is provided in Attachment B. The applicant must obtain permission from or make offers to pay to everyone appearing on the Agency's most recent list of the Data Submitters List and any other person identified by EPA as a prior submitter of relevant data.

IV. Rights And Obligations Of Data Submitters.

A. Responding to "Data Gap" Letters.

As explained in section II.B.3, applicants using 40 CFR Part 158 to identify data requirements are required to contact all original data submitters if they wish to claim that a data gap exists. Data submitters are not required to respond to these notices. However, if a data submitter fails to respond within 60 days, he may have waived his right to contest an applicant's claim that a data gap exists. The Agency will presume that no data satisfying a particular requirement exist if the applicant certifies in his application that:

1. He has furnished notice as described in paragraph II.B.3. of this Notice identifying the alleged data gap; and

2. No data submitter has informed the applicant in writing within 60 days that he has submitted valid data satisfying the requirement.

This presumption may be overcome only if the data submitter shows good cause for the failure to provide timely notice to the applicant and acts promptly to provide such notice once it becomes possible. A data submitter cannot overcome this presumption merely by providing notice to EPA (but not to the applicant) that data satisfying a particular data requirement have previously been submitted to EPA.

Under the Selective Method, an applicant may cite another person's data only if the applicant has obtained the original data submitter's permission or has made a proper offer to pay compensation to the original data submitter for data not entitled to exclusive use protection. The data submitter is not required to give his permission and does not do so merely by responding to a "data gap" letter. Nor does a "data gap" letter constitute a proper offer to pay compensation unless it is accompanied by the tender of a proper offer.

B. Supplying Lists of Data Requirements and Submitted Data.

A data submitter may supply to the Agency a list of what he believes to be the data requirements for a particular kind of product. A data submitter may also supply to the Agency a list of applicable, valid data that he has submitted on any particular active ingredient. Any such list shall be made available to the public on request, to the extent permitted by law. As described in sections V.A. and B. of this notice, EPA will review such submissions by original data submitters in determining whether applicants have complied with this notice.

C. Notification for Applications Involving "Exclusive Use" Data.

If a product acceptable for registration contains an active ingredient for which data subject to exclusive-use protection have been submitted to the Agency, the Agency will notify all persons who have submitted data on that ingredient of the proposed action. Specifically, thirty days prior to approval of such an application, EPA will notify the applicant and original data submitters of the proposed registration and of the Agency's decision on any points as to which there was a disparity between the application materials and any lists of data or data requirements provided by the original data submitters.3/

V. Agency Review Of Applications.

A. Applications Relying on the Selective Method.

EPA will review applications relying on the Selective Method to determine whether the applicant has listed all data requirements applicable to his product; the applicant has satisfied each data requirement by using one of the methods listed in section II.B.; the "new" data submitted by the applicant are valid; the applicant generated, has all relevant rights to, has permission to rely on, or has made a proper offer to pay compensation for all data submitted or cited.

1. Review Of An Applicant's Data Requirements List. EPA will review the list of data requirements submitted by an applicant to determine whether all applicable requirements have been identified. Where a data submitter has supplied a list of requirements to EPA, the Agency will compare this list with the applicant's list of data requirements. In addition, in case of conflict between applicants and previous data submitters which cannot be resolved by other means, EPA may review the studies in its files to determine whether the data would lead to the imposition of any additional conditional data requirements not listed by the applicant.

3/ In response to concerns expressed by some firms about the meaning of statutory provisions governing consideration of previously submitted data, during the period in which this Notice is in effect EPA will, at the request of any applicant for registration of a product containing any active ingredient on which another person has previously submitted data entitled to exclusive use protection under sec. 3(c)(1)(D)(i), or at the request of any such previous data submitter, voluntarily attempt to evaluate the risks, benefits, and registrability of the applicant's product based solely upon the data submitted or cited with the application. The Agency's conclusions about the registrability of such a product on that basis will be made available to the applicant and the original data submitter as part of the 30-day notice set forth in this paragraph IV.C. The actual registration decision for any such product will be based on the procedures described in this notice for all products.

If the Agency concludes that an applicant has failed to list an applicable data requirement, the Agency will refuse to register the product and will promptly notify the applicant of its determination. The Agency notes, however, that approval of a registration does not represent a waiver of any applicable data requirement not listed by the applicant.

2. Review of an Applicant's Data Submissions. As noted in section II.B., applicants should submit only those data which have not previously been provided to the Agency. EPA will conduct an independent scientific review of all major tests which are being supplied to the Agency for the first time to determine whether they are valid (i.e., whether they supply scientifically useful information), and whether they fulfill an Agency data requirement (i.e., whether the data provide sufficient information to permit EPA to adequately assess a particular property of the pesticide on which data are required, such as its teratogenicity or persistence).

The Agency will not necessarily review data submitted or cited by the applicant which have previously been submitted to the Agency, and approval of a registration does not constitute a finding by the Agency that such studies are valid. If, however, the Agency determines that data submitted or cited by an applicant are not valid or do not fulfill the requirements for which they were submitted or cited, the Agency will refuse to register the product and will promptly notify the applicant of its conclusion.

In addition, where a data submitter supplies a list of data that he has submitted to the Agency, EPA will attempt to ensure that the applicant is not relying on such data without either having obtained permission or having submitted a proper offer to pay in connection with the pending application, and has not improperly claimed a data gap to exist.

B. Review of Applications Using the Cite-All Method.

EPA will review applications using the Cite-All Method to determine whether an applicant has submitted the appropriate proof of permission to cite any data as to which he claims permission has been granted and any data entitled to exclusive use protection. EPA will also determine whether an applicant has submitted an appropriate certification that proper offers to pay have been submitted to all submitters of relevant data who have not granted permission to the applicant to cite data which they have submitted.

C. Public Availability of Registration Application Materials.

The Agency will rely on data submitters to monitor compliance with the procedures and requirements for registration. In this regard, the Agency will periodically make available to the public a list of applications which have been approved, including:

1. The registrant's name and address;

2. The product's name and registration number;

3. The date of registration;

4. The active ingredient(s) in the product; and

5. The method of support used.

On request, following approval of an application using the Selective Method of data support, the Agency will make available, to the extent legally permitted, an applicant's list of data requirements and list of submissions purporting to satisfy each data requirement. Similarly, on request and following approval of an application using the cite all method of data support, the Agency will make available, to the extent legally permitted, the certifications and other documents submitted to demonstrate compliance with these procedures.

VI. Challenges to Registration Actions Based on These Procedures.

Any data submitter who is adversely affected by the issuance of a registration on the ground that the application (or EPA's approval of it) failed to comply with Section I through V this Notice may file a written petition with the Agency requesting that EPA cancel the registration of the product. The petition should state that the petitioner has previously submitted to EPA data which would fulfill each data requirement the petitioner claims the applicant has failed to satisfy. The petition should also describe the manner in which the applicant has failed to satisfy the data requirements for the product. The grounds for such a petition could include:

(A) The applicant has failed to list a data requirement applicable to his product, or to satisfy all applicable data requirements;

(B) The applicant has submitted or cited a study that is not valid or that does not fulfill the data requirement in connection with which it was submitted or cited;

(C) The applicant has failed to comply with the procedures for showing that a data gap exists, or has improperly represented that a data gap exists;

(D) The applicant has failed to comply with the procedures for demonstrating that he either has permission to cite or has made a proper offer to pay compensation where he has cited a study which is not his own;

(E) The applicant has cited without permission data which are entitled to exclusive use protection under FIFRA sec. 3(c)(1)(D)(i); or

(F) The applicant has submitted any false certification or statement to the Agency.

EPA will furnish a copy of the petition to the registrant in question. The Agency will consider written comments responding to the petition submitted within 60 days after the date on which the petition is received by the registrant.

EPA will review petitions and any comments on them to determine whether they present a substantial basis for arguing that the registration of a pesticide should be cancelled. If EPA determines that a petition is without merit, it will deny the petition. If, on the other hand, the Agency concludes that a petitioner has shown a possible violation of the registration procedures and that such a violation may have deprived the petitioner of legal rights involving previously submitted data, EPA will issue either a Notice of Intent to Cancel Registration under FIFRA sec. 6(b)(1) or a Notice of Intent to Hold a Hearing under FIFRA sec. 6(b)(2).4/

The purpose of such a hearing will be to determine whether the claims made in the petition are true, and if so, whether the registrant failed to satisfy the requirements of this Notice. Any such hearing will be conducted under the procedures described in EPA's Rules of Practice, 40 CFR Part 164. At the conclusion of a hearing, if the Agency determines that an applicant failed to comply with the requirements of this Notice, EPA will cancel the registration which was based on that application.

EPA notes that where a proper offer to pay has been tendered to a data submitter, EPA will review a petition to cancel only after the applicant and data submitter have availed themselves of the negotiation and arbitration procedures provided for in the Act, and only upon the grounds specified in the Act pertaining to failure to comply with agreements that have been negotiated or arbitrated.

VII. Agency Review of Applications Under Risk/Benefit Criteria.

If the Agency determines that the applicant has supported its application adequately under either the Selective or Cite-All procedures, the Agency will determine whether the product meets the other standards for registration in FIFRA sec. 3(c)(5) or 3(c)(7). The Agency will

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4/ Prior to issuing such a Notice, EPA may inform the registrant and petitioner of its preliminary assessment and allow a brief period during which efforts can be made to resolve the matter informally.

perform as extensive a review as necessary to determine whether the application meets those statutory standards, and the Agency will not limit its review of data solely to those studies submitted or cited by the applicant. The Agency also will determine whether the results of any newly submitted tests alter any prior regulatory judgments it may have reached about the registrability of products such as the applicant's.5/ Except as provided above, EPA will issue registrations for any pesticide product as soon as it determines that the product is acceptable.

VIII. Effect on Pending Applications.

Persons with applications for registration actions pending before the Agency who wish to resubmit or modify those applications as necessary to take advantage of the opportunity to cite data pursuant to an offer to pay compensation as set forth in this Notice may do so by promptly notifying the appropriate Product Manager.

IX. Further Information.

If you wish additional information on this Notice, please contact either a Product Manager in the Registration Division or Jean Frane at (703) 557-0592.

Douglas D. Campt
Director, Registration Division

Attachments (3)

5/ EPA will also continue its present practice of attempting to determine whether differences in test results are attributable to differences in composition of the substances tested and, if they are, of evaluating the regulatory significance of those composition differences.

ATTACHMENT A
FORMULATOR'S EXEMPTION STATEMENT

EPA File Symbol/Reg. No. _____ Product Name _____

Applicant's Name and Address _____

_____

_____

As an authorized representative of the applicant for registation of the product identified above, I hereby certify that:

(1) Our product is an end use product, and it contains the active ingredient(s): _____

_____

_____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling the appropriate text which paragraph applies--(A) or (B):

(A) An accurate Confidential Statement of Formula for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active Ingredient	Source: Product Name and Reg. No.
_____	_____
_____	_____
_____	_____

Signature: _____

Typed name: _____

Dated: _____

ATTACHMENT B

CERTIFICATION WITH RESPECT TO OFFER TO PAY AND GENERAL OFFER TO PAY

EPA File Symbol/Reg. No. _____ Date of application _____

Name of Product _____

Applicant's Name and Address _____

_____

_____

_____

I certify that, for each study listed in the list of data requirements under Section II.A. of PR Notice 84-4 that is not entitled to exclusive use protection:

1. I have obtained the written permission of the original data submitter to cite that study in support of his application; or

2. I have notified in writing by certified mail the companies who have submitted data I have cited to support this application and have offered to: (1) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (2) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA, and the amount and terms of compensation due, if any.

The companies I have notified are: (Check one)

[ ] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-All method).

[ ] Those companies who have submitted the studies which I have cited (Selective method).

I hereby offer and agree to pay compensation to other parties, with regard to the approval of this application, to the extent required by section 3(c)(1)(D) and section 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

Signature: _____

Title: _____

Date: _____

ATTACHMENT C

CERTIFICATION OF COMPLIANCE WITH "DATA GAP" PROCEDURES

EPA File Symbol/Reg. Number _____ Date of application _____

Name of Product _____

Applicant's Name and Address

_____

_____

_____

_____

I certify that:

1. I have notified by certified mail, return receipt requested, each person on the Pesticide Data Submitters' List for each active ingredient in this product, in accordance with the requirements of section II.B.3. of PR Notice 84-4; and

2. I have waited 60 days following such notice;

3. I have received no response indicating that any person has submitted a valid study that would satisfy any of the requirements for which a data gap is claimed, and therefore I have no basis for believing that such data have been submitted by any other person.

Signature _____

Title _____

Date _____